DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4093 '99 MAY -4 A10:10

APR 29 1999

Denavir™
Docket No.: 98E-0487

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,075,445, filed by Beecham Group p.l.c., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Denavir™, the human drug product claimed by the patent.

The total length of the regulatory review period for Denavir™ is 1,299 days. Of this time, 954 days occurred during the testing phase and 345 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 7, 1993.

   The applicant claims March 5, 1993, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 7, 1993, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: October 16, 1995.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for Denavir ™ (NDA 20-629) was initially submitted on October 16, 1995.

3. The date the application was approved: September 24, 1996.

   FDA has verified the applicant's claim that NDA 20-629 was approved on September 24, 1996.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Dara L. Dinner, Esq.
SmithKline Beecham Corp.
Corporate Intellectual Property--UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

DATE: APR 2 9 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Denavir™
Docket No. 98E-0487, FRDTS# OC99113

Attached is a FR Notice for the human drug product, Denavir™. This document has been internally reviewed and cleared by OHA.

Please note that Denavir™ is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

98E-0487

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

2506 '99 MAY -4 A9:48

Memorandum

Date: APR 29 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for Denavir™

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0487** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,075,445**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.